



CERTIFICATE OF ANALYSIS

This certificate is provided to confirm that the diagnostic kit specified below conforms to the production and testing specifications required by Cepheid’s Quality System, in compliance with the US Food and Drug Administration’s Quality System Requirements, ISO 13485, European IVD Directive and the Canadian Medical Devices Regulations (CMDR).

Product Name: Xpert® GBS LB XC

Cepheid Catalogue Part No.: GXGBSLBXC-10

Kit Lot No.: 1001460208

Cartridge Lot No.: 13202

Kit Expiration Date: 2026-11-29

<u>Legal Manufacturer</u> Cepheid 904 Caribbean Drive Sunnyvale, CA 94089 USA	<u>Manufacturing Facility</u> <input checked="" type="radio"/> Solna <input type="radio"/> Sunnyvale <input type="radio"/> Newark Cepheid AB Röntgenvägen 5 SE-171 54 Solna Sweden <input type="radio"/> Lodi
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Functional Testing according to D68621 Rev: A

<i>Test Description</i>	<i>Acceptance Criteria</i>	<i>Test Result</i>
Positive	GBS POSITIVE	Passed
Negative	GBS NEGATIVE	Passed

If checked this document is produced electronically and valid without a wet signature.

Anton Andersson 2024-12-13
Signature of Quality Assurance, Date

Name: Anton Andersson Engström

Title: QA Analyst